

An audit of adverse drug reactions to aqueous cream in children with atopic eczema

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AIM • To determine the proportion of children with atopic eczema who develop cutaneous reactions to emollient creams and ointments.

DESIGN • Audit of immediate cutaneous reactions to emollient creams and ointments. The percentage of episodes of exposure to aqueous cream associated with immediate cutaneous reactions was compared with the percentage of episodes of exposure to all other emollients associated with these reactions.

SUBJECTS AND SETTING • The notes of 100 children aged 1 to 16 with atopic eczema attending a paediatric dermatology clinic at the Sheffield Children's Hospital.

OUTCOME MEASURE • A history of an immediate cutaneous reaction, defined as one or more of burning, stinging, itching and redness, developing within 20 min-

utes of applying an emollient to the child's skin was recorded.

RESULTS • 56% of the episodes of exposure to aqueous cream were associated with an immediate cutaneous reaction. Of the 622 episodes of exposure to all other emollients, 111 (17.8%) were associated with an immediate cutaneous reaction. The difference was statistically significant ($P < 0.001$).

CONCLUSION • The key to successful emollient therapy is education and tailoring the treatment to the individual child. Cutaneous reactions are one consideration; others include cosmetic acceptability and quantity applied. In our hospital this service is provided by specialist nurses, pharmacists and dermatologists. Community pharmacists could make a major contribution in this area by actively encouraging effective emollient use.

The stratum corneum of the skin provides a barrier preventing the penetration of irritants and allergens. In atopic eczema there is a primary defect in the skin barrier which allows the loss of water from the corneocytes. As a result the corneocytes shrink and cracks open between them which permits the penetration of irritants and allergens¹ triggering the development of eczematous lesions. The use of soap on the skin of individuals with atopic eczema produces a further deterioration of the skin barrier.^{2,3} The use of a comprehensive emollient regimen including emollient creams and ointments, bath oils and soap substitutes restores the epidermal barrier and is the first line treatment for atopic eczema.⁴ Indeed, emollients have been used in the management of diseases such as atopic eczema for around 5,000 years.

It has been established that compliance with simple oral treatment regimens sufficient to achieve the desired therapeutic outcome occurs in only 50 per cent of patients. Compliance with the complex treatment regimens for managing atopic eczema is likely to be much less than 50 per cent. An audit of new referrals to our paediatric dermatology clinic revealed that none of the children was being treated with emollients or topical steroids in accordance with best practice guidelines.^{5,6} Intensive education from specialist dermatology nurses resulted

in an 800 per cent increase in the use of emollients and an appropriate use of mild and moderate potency topical steroids. This resulted in an 89 per cent reduction in the severity of the eczema.

Finding the most suitable emollient for an individual may be a matter of trial and error.⁷ In theory, greasier, oil-based products are more effective but these are rarely tolerated and therefore are not used by people with mild or moderate atopic eczema. In order to enhance children's compliance with their treatment regimens we have developed a child-oriented approach — "Skin Wars!" — to teach them about eczema and its treatment.⁸

Part of this education allows children to pick their favourite emollient from a tray containing all of the emollients in the BNF.

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This method empowers them to use their chosen emollients. During this process we ask the children and parents to report any previous adverse reactions to them. These reactions manifest as a burning, stinging and redness of the skin after the application of the emollient. We noticed that adverse reactions following the use of aqueous cream in children were more frequent than to any other emollient cream or ointment.

Adverse reactions to aqueous creams have been previously reported.⁹ In *The Pharmaceutical Journal* Lapsley¹⁰ asked whether aqueous cream should no longer be a first choice emollient in view of the large number of irritant reactions which it caused. His letter triggered several replies to *The Journal*, for example, that from Furniss,¹¹ which emphasised the lack of "good quality evidence comparing preparations". This statement was a fair reflection of the paucity of data regarding the efficacy and tolerability of emollients.¹² We therefore decided to conduct an independent audit of cutaneous adverse reactions to emollients in children attending our atopic eczema clinic.

METHODS

An audit of cutaneous adverse reactions to emollients was conducted in our paediatric dermatology clinic in 2002. An anonymised form was completed from the notes and during clinic visits for 100 children with

Key points

- Cutaneous reactions to aqueous cream in children with atopic eczema are so common that it should only be used as a soap substitute and not as a "leave on" emollient.
- Several of the children in this audit reported that aqueous cream caused stinging when used as a "leave on" emollient but not when used as an emollient wash product. The problem is not with the constituents of wash products but how they are used. In support of this mechanism.
- Finding the most suitable emollient for an individual may be a matter of trial and error.⁷ The best emollient for an individual is the one they prefer because they will use it regularly and it will therefore be effective.

atopic eczema aged 1 to 16 years. All of the emollients available in the BNF were recorded, including cream and ointment formulations. Immediate cutaneous reactions were defined as a report of one or more of burning, stinging, itching and redness developing within 20 minutes of applying an emollient to the child's skin.

RESULTS

An initial review of the audit results indicated that there was a large proportion of children reporting cutaneous reactions following the applications of aqueous creams. The cutaneous reactions reported following all other emollients were similar and occurred much less frequently. There were

14 other emollient creams or ointments which had been used. There were, therefore, insufficient numbers using each of the other emollient creams and ointments to detect statistical differences between them. A comparison was therefore made between cutaneous reactions following exposure to aqueous cream with cutaneous reactions following exposure to all other emollients.

Of the 100 children audited, 71 had used aqueous cream and of these 40 (56.3 per cent) had developed an immediate cutaneous reaction.

The 100 children had also been exposed to an average of 6.2 other emollients (excluding aqueous cream). This meant that there were 622 episodes of exposure to all of the other emollients resulting in 111 immediate cutaneous reactions (17.8 per cent). We compared these two percentages and the difference was statistically significant using the chi-squared test ($P < 0.001$).

DISCUSSION

Various forms of discomfort can be caused by topical agents. The best described is "stinging".⁹ These reactions are not allergic and may occur with any emollient. This audit indicates that discomfort on application is more common in children using aqueous cream than in those using other emollients. There were insufficient numbers of children using the other emollient products to detect differences between them.

If a particular emollient causes an adverse reaction, the child and parent will not use it and it will be of no benefit. Some patients report that they react to aqueous cream obtained in one part of the UK and not another. One possible explanation might be that aqueous cream is provided by a number of manufacturers and the use of

different preservatives is permitted. This problem was highlighted in a letter to *The Pharmaceutical Journal* reporting cutaneous reactions to the formulations of aqueous cream containing phenoxethanol but not those containing chlorocresol.¹³

Another important consideration is that aqueous cream was originally designed as a wash product rather than a "leave on" emollient. Ingredients such as antiseptics and surfactants are important and safe constituents of wash products because they are only transiently in contact with the skin. These ingredients may also be used in "leave on" products but at a much lower concentration than in bath products.

Severe irritant reactions have been reported following the use of excessive concentrations of antiseptic emollient bath products. This results in a trapping of significant residues of the antiseptic in body folds, leaving a high concentration of the antiseptic in contact with the skin.¹⁴ The problem is not with the constituents of the wash products but rather how they are used. In support of this mechanism several of the children in this audit reported that aqueous cream caused stinging when used as a "leave on" emollient but not when used as an emollient wash product.

Ensuring optimum compliance with topical treatment regimens for atopic eczema is dependent on comprehensive education and tailoring topical treatments to individual children.^{3,4,6,15-17} Cutaneous reactions are one consideration; others include cosmetic acceptability, quantity applied and temperature of the emollient. In our hospital, comprehensive education is provided by specialist paediatric nurses, pharmacists and dermatologists. Community pharmacists could make a major contribution in this area by actively encouraging effective emollient use.⁷

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